

PATENT COOPERATION TREATY

<p>From the INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY GlaxoSmithKline</p>							
<p>To:</p> <p>WALKER, Ralph, Francis GlaxoSmithKline Corporate Intellectual Property (CN 980 Great West Road Brentford, Middlesex TW8 9GS GRANDE BRETAGNE</p>	<p>Corporate IP Received BRENTFORD</p> <p>13 DEC 2004</p> <table border="1"> <tr> <td>ATTY FILED</td> <td>ADM'D</td> </tr> <tr> <td>IPM:TM</td> <td>ON UPDATED ON:</td> </tr> <tr> <td colspan="2">ATTY CHECKED/FILED</td> </tr> </table> <p>Date of mailing (day/month/year)</p>	ATTY FILED	ADM'D	IPM:TM	ON UPDATED ON:	ATTY CHECKED/FILED	
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<p>PCT</p> <p>NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL PRELIMINARY EXAMINATION REPORT (PCT Rule 71.1)</p>							

PCT

NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL PRELIMINARY
EXAMINATION REPORT

(PCT Rule 71.1)

ATTY CHECKED/PC	Date of mailing (day/month/year)	09.12.2004
Applicant's or agent's file reference RFW/B45320	IMPORTANT NOTIFICATION	
International application No. PCT/EP 03/10349	International filing date (day/month/year) 15.09.2003	Priority date (day/month/year) 17.09.2002
Applicant GLAXOSMITHKLINE BIOLOGICALS S.A. et al.		

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. REMINDER

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

The applicant's attention is drawn to Article 33(5), which provides that the criteria of novelty, inventive step and industrial applicability described in Article 33(2) to (4) merely serve the purposes of international preliminary examination and that "any Contracting State may apply additional or different criteria for the purposes of deciding whether, in that State, the claimed inventions is patentable or not" (see also Article 27(5)). Such additional criteria may relate, for example, to exemptions from patentability, requirements for enabling disclosure, clarity and support for the claims.

<p>Name and mailing address of the international preliminary examining authority:</p> <p> European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Fax: 523656 epmu d Fax: +49 89 2399 - 4165</p>	<p>Authorized Officer</p> <p>Loepke, S</p> <p>Tel. +49 89 2399-2569</p> <p></p>
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PATENT COOPERATION TREATY
PCT
INTERNATIONAL PRELIMINARY EXAMINATION REPORT
(PCT Article 36 and Rule 70)

Applicant's or agent's file reference RFW/B45320	FOR FURTHER ACTION <small>See Notification of Transmittal of International Preliminary Examination Report (Form PCT/A/416)</small>	
International application No. PCT/EP 03/10349	International filing date (day/month/year) 15.09.2003	Priority date (day/month/year) 17.09.2002
International Patent Classification (IPC) or both national classification and IPC B65G17/32		
Applicant GLAXOSMITHKLINE BIOLOGICALS S.A. et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 8 sheets, including this cover sheet.

This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 6 sheets.

3. This report contains indications relating to the following items:

- I Basis of the opinion
- II Priority
- III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV Lack of unity of invention
- V Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI Certain documents cited
- VII Certain defects in the international application
- VIII Certain observations on the international application

Date of submission of the demand 22.03.2004	Date of completion of this report 09.12.2004
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 opmu d Fax: +49 89 2399 - 4465	Authorized Officer  Lawder, M Telephone No. +49 89 2399-8465

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INTERNATIONAL PRELIMINARY
EXAMINATION REPORT

International application No. PCT/EP 03/10349

I. Basis of the report

1. With regard to the elements of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

Description, Pages

1-33 as originally filed

Claims, Numbers

1-33 filed with telefax on 25.11.2004

Drawings, Sheets

1-16 as originally filed

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- the language of publication of the international application (under Rule 48.3(b)).
- the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- contained in the international application in written form.
- filed together with the international application in computer readable form.
- furnished subsequently to this Authority in written form.
- furnished subsequently to this Authority in computer readable form.
- The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- the description, pages:
- the claims, Nos.:
- the drawings, sheets:

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**International application No. PCT/EP 03/10349

5. This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

the entire international application,

claims Nos. 24

because:

the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify):

the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

no international search report has been established for the said claims Nos. 24

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

the written form has not been furnished or does not comply with the Standard.

the computer readable form has not been furnished or does not comply with the Standard.

IV. Lack of unity of invention

1. In response to the invitation to restrict or pay additional fees, the applicant has:

restricted the claims.

paid additional fees.

paid additional fees under protest.

neither restricted nor paid additional fees.

2. This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

complied with.

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**International application No. PCT/EP 03/10349 not complied with for the following reasons:

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

 all parts. the parts relating to claims Nos. .**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. Statement**

Novelty (N)	Yes: Claims	1-23,25-33
	No: Claims	
Inventive step (IS)	Yes: Claims	1-23,25-33
	No: Claims	
Industrial applicability (IA)	Yes: Claims	1-23,25-33
	No: Claims	

2. Citations and explanations

see separate sheet

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**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/EP 03/10349

Item IV:

1. The application lacks unity within the meaning of Rule 13 PCT for the following reasons:
 - a) The subject-matter of claims 1-21 and 25 (invention 1) concerns a holding means for an article and conveyor system, the holding means comprising a base part and a grip part;
 - b) the subject-matter of claims 22 and 23 (invention 2) concerns a conveyor system and process for filling a vial through a hollow needle; and
 - c) the subject-matter of claims 26-33 (invention 3) concerns a processing station for performing an operation on an article in a laminar flow of purified air, an aerodynamic shroud being placed around the processing apparatus.

There are no common inventive features linking the independent claims of the three inventions, such that the examining division considers that the separate inventions are not so linked as to form a single general inventive concept (Rule 13.1 PCT).

Item V:

2. The following documents (D) are referred to in this communication; the numbering will be adhered to in the rest of the procedure:

D1: US-A-3 881 763
D2: WO 02 064439 A
D3: US-A-2 503 147
D4: US-A-6 098 676
D5: EP-A-0 096 336.

3. Invention 1 (claims 1-21, 25)

- 3.1 Document D1 discloses a holding means (chuck) suitable for lifting articles 124 having upward and downward facing surfaces onto a conveyor 116 for transporting the articles thereon, comprising:

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EXAMINATION REPORT - SEPARATE SHEET**

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a base (receiver 72 and resilient disc 80) suitable for the upward facing surface to sit upon;

a grip part 88 positioned relatively downwardly of the base and suitable to bear on the downward facing surface;

the base and grip part being moveable so that the article may be positioned between the base and the grip part, and the base and grip part may then be brought closer together to grip the article between the base and the grip part, and subsequently moved further apart to release the article (see figs 9 & 10 A, B, C, D, E).

However, the conveyor 116,118 of D1 is described as an overhead conveyor and operates by lifting the articles off a lower conveyor 122, whereas the subject-matter solves the problem of holding articles onto a conveyor.

None of the available prior art show or suggest the combination of features of claim 1 for holding articles onto a conveyor.

The subject-matter of claim 1 is therefore new and inventive within the meaning of Article 33(2) and (3) PCT.

3.2 Claims 2-21 are dependent on claim 1 and as such also meet the requirements of the PCT with respect to novelty and inventive step.

3.3 The process of claim 25 (dependent on the conveying system of claim 14 which is dependent on the holding means according to claim 1) uses the holding means of claim 1 and is therefore also novel and inventive.

4. Invention 2 (claims 22 and 23)

4.1 Document D3 discloses a conveyor system (racks 24 and endless chains 32) provided with a processing station (filling machine) to perform a process in which a vial 12 with its closure 14 made of a self sealing material such as rubber is punctured by passing a hollow filling needle 114 through the closure, a material introduced into the vial via the needle and the needle withdrawn, provided with means 64 to resist the upward force of withdrawing the filling needle (col. 6, lines 51-53; "first the injecting means 1 is raised, and then the positioning frame 64").

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/EP 03/10349

The subject-matter of claim 22 differs from D3 in that the vial closure is made of a heat-fusible puncturable material and that the means to resist the upward force of withdrawing the filling needle hold the vial adjacent to the base of the vial.

This feature, which avoids the positioning of any holding means near to the vial mouth, is not known nor suggested by the available prior art.

The subject-matter of claim 22 is therefore new and inventive within the meaning of Article 33(2) and (3) PCT.

4.2 Claim 23 is dependent on claim 22 and as such also meets the requirements of the PCT with respect to novelty and inventive step.

5. Invention 3 (claims 26-33)

5.1 Document D4 discloses a processing station (fill-seal machine) for performing an operation on an article in a flow of purified air, which comprises:
- a processing apparatus for performing the operation upon the article, having an aerodynamic shroud (duct 32) around at least part of the apparatus.

The subject-matter of independent claim 26 differs from the known processing station of D4 in that the operation is carried out in a laminar upstream to downstream direction flow of purified air, and that the aerodynamic shroud around at least part of the apparatus is positioned such that a leading surface of the shroud is upstream of the apparatus.

The object of the aerodynamic shroud being to improve the laminar flow of purified air through the system.

Even though D5 discloses a perpendicular (left to right) laminar flow around containers to be filled, there is no suggestion from the available prior art to position an aerodynamic shroud such that a leading surface of the shroud is upstream of the apparatus.

Claim 26 is therefore new and inventive within the meaning of Article 33(2) and (3) PCT.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT - SEPARATE SHEET International application No. PCT/EP 03/10349

5.2 Claims 27-33 are dependent on claim 26 and as such also meet the requirements of the PCT with respect to novelty and inventive step.